K122619

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510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

510(K) Submitter:

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OCT 2 2012

Contact Person:

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Date of Preparation: August 24, 2012

Trade Name: Epix® Suction Irrigation System

Common Name: Suction Irrigator

Classification:

Table 5-1 - Classifications

Product Code	Regulation	Classification
GCX	21 CFR 880.6740	Vacuum-powered Body Fluid Suction Apparatus
HET	21 CFR 884.1720	Gynecologic Laparoscope and accessories
KQT	21 CFR 876.4370	Gastroenterology-urology evacuator

Predicate Device:

Stryker® Cassette Pump
510(k) #: K042454
Product codes: GCX, HET, KQT

Device Description:

The Epix Irrigation Pump (model C7000) is reusable and operates outside of the sterile field. The Epix Suction Irrigation Tubing Set (model C7100) is a sterile, single use device, used in conjunction with the Epix Irrigation Pump and the house vacuum to deliver sterile irrigation fluids and to evacuate blood, tissue debris, and smoke from the surgical site.

Intended Use:

The Epix® Suction Irrigation System is intended as a general purpose suction and/or irrigation device for use in laparoscopic and open general surgery, laparoscopic and open gynecological surgery, laparoscopic and open urologic surgery. This device delivers sterile irrigant solution and serves as a conduit for suction.

Summary of Technological Characteristics:

The Epix® Suction Irrigation System is substantially equivalent in safety and effectiveness to the Stryker® Cassette Pump (K042454).

The subject and predicate systems are technologically similar in that they are both designed to provide controlled suction from and irrigation to the operative site during laparoscopic and open procedures. For each device, the pump is capable of increasing the rate of fluid delivery and has multiple flow rate settings. The tubing set connects with IV fluid bags and the house vacuum. Suction and irrigation are actuated by the valves on the handpiece. Both systems flush blood and tissue debris from the operative site during surgery.

Discussion of Testing:

The Epix Suction Irrigation System is designed to the following safety and performance standards: IEC 60601-1 Medical electrical equipment – General requirements for safety, IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests, and ISO 10993 Biological Evaluation of Medical Devices.

Applied Medical created a testing protocol to confirm substantial equivalency between the subject and predicate. The devices were tested side-by-side to evaluate substantial equivalence in performance in a laboratory setting. The bench top tests seen in Table 5-2 were designed to focus on the functional performance of both the suction and irrigation features.

Table 5-2 - Performance Tests

Irrigation	Suction
Irrigation Fluid Flow Test	Aspiration Fluid Flow Test
Irrigation Fluid Leak Test	Smoke Evacuation Flow Test

The subject device was also evaluated by a tubing collapse test based on an applicable section of ISO 10079-3 – Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source.

Conclusions Drawn from Testing:

Testing demonstrates that the subject Epix Suction Irrigation System is substantially equivalent to the predicate Stryker Cassette Pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Applied Medical
% Ms. Jessica Cho
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OCT 2 2012

Re: K122619
Trade/Device Name: Epix® Suction Irrigation System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: BTA
Dated: August 24, 2012
Received: August 28, 2012

Dear Ms. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122619

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Epix® Suction Irrigation System

Indications for Use: The Epix® Suction Irrigation System is intended as a general purpose suction and/or irrigation device for use in laparoscopic and open general surgery, laparoscopic and open gynecological surgery, and laparoscopic and open urologic surgery. This device delivers sterile irrigant solution and serves as a conduit for suction.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K122619